In the United States Court of Federal Claims

DONNA BALDWIN, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	No. 13-957 V Filed: December 2, 2020* Reissued for Public Availability: December 17, 2020

For Petitioner: F. John Caldwell, Jr., Maglio Christopher & Toale, P.A., Sarasota, FL

For Defendant: Lisa A. Watts, Senior Trial Attorney, Torts Branch, Civil Division, U.S. Department of Justice, Washington, D.C.

MEMORANDUM AND ORDER

Petitioner, Donna Baldwin, seeks review of a decision issued by Special Master Daniel T. Horner, who concluded that Petitioner is not entitled to an award of compensation. *See Baldwin v. HHS*, No. 13-957V, slip op. (Fed. Cl. Spec. Mstr. June 4, 2020) (ECF No. 104) (Dec. or Decision). Petitioner alleges that the Special Master erred in finding that Petitioner did not meet her burden under *Althen* prongs one and two. Pet'r's Mot. for Review (ECF No. 106); *see also* Pet'r's Mem. of Objs. in Support of Mot. for Review (ECF No. 107) (Pet'r's Br.).

Respondent requests this Court affirm the Special Master's decision. Resp't's Mem. in Resp. to Pet'r's Mot. for Review at 7 (ECF No. 109) (Resp't's Br.). Respondent argues that

*Pursuant to Rule 18(b) of the Vaccine Rules of the United States Court of Federal Claims (Appendix B to the Rules of the United States Court of Federal Claims), the Court filed this Memorandum and Order on December 2, 2020, and provided the parties fourteen (14) days to propose redactions. The parties did not propose redactions. Accordingly, the Court is publicly reissuing its Memorandum and Order in its original form for publication.

Petitioner failed to provide a reliable medical theory causally connecting the influenza (flu) vaccine to her ventricular fibrillation and failed to identify objective evidence in her contemporaneous medical records to support her experts' proffered theories of causation. Resp't's Br. at 1-2.

For the reasons stated below, Petitioner's Motion for Review is **DENIED**, and the Special Master's Decision denying entitlement is **SUSTAINED**.

Factual and Procedural Background

On December 5, 2013, Petitioner filed a petition for compensation with the National Vaccine Injury Compensation Program (Vaccine Program), under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1–300aa-34 (2012) (Vaccine Act), for an off-table injury. Petition ¶ 1 (ECF No. 1) (Pet.). Specifically, Petitioner alleged that six days after her flu vaccination, under the Fluvirin brand, Petitioner experienced a ventricular fibrillation and cardiac arrest. Pet. at ¶¶ 2-3; *see also* Pet'r's Ex. 9 at 21. To support her position, she provided various medical records[1] and expert reports[2]. Respondent filed competing expert opinions[3] to support its position that Petitioner's cardiac event was caused by factors other than her vaccine. Petitioner's medical records and the parties' expert opinions are summarized in detail below.

[1] Petitioner initially filed medical records marked as Exhibits 1-21 (ECF No. 4) and Exhibits 22-23 (ECF No. 8). She later filed additional medical records marked as Exhibit 24 and a Statement of Completion on April 14, 2014. (ECF Nos. 9-10). However, after filing her Statement of Completion, Petitioner filed medical records again on May 28, 2015 (ECF No. 35) (Exhibits 30-34) and August 30, 2018 (ECF No. 79) (Exhibits 44-48). *See also* ECF Nos. 81, 83, 89, 90, 96.
[2] Petitioner filed reports by two experts: Dr. Robert A. Waugh (ECF Nos. 18, 19, 32, 38, 44) and Dr. Robert M. Stark (ECF No. 74).
[3] Respondent filed reports by two experts: Dr. Laurence Sperling (ECF Nos. 41, 50) and Dr. Shane LaRue (ECF Nos. 72, 75, 77).

I. Petitioner's Medical Records

At the time of the flu vaccination at issue, Petitioner was fifty-four (54) years old, and had several pre-existing conditions. *See* Pet'r's Ex. 21 at 19 (listing Petitioner's date of birth and date of vaccination). Based on Petitioner's medical records, the Special Master found that prior to receiving the vaccination at issue, "[p]etitioner [had] a history of various medical issues including muscle spasm, chronic fatigue syndrome, obesity, anemia, hypothyroidism, hyperlipidemia and dyslipidemia, hypertension, anxiety, depression, and diabetes." Dec. at 5 (citing Pet'r's Ex. 2 at 25; Pet'r's Ex. 3 at 3; Pet'r's Ex. 5 at 2; Pet'r's Ex. 6 at 2, 8; Pet'r's Ex. 9 at 3, 14; Pet'r's Ex. 14 at 2). On September 8, 2009, Petitioner visited a primary care doctor and complained of dizziness and heart palpitations characterized by a rapid heartbeat that had been occurring for an uncertain time period. Pet'r's Ex. 6 at 30. She was noted to be morbidly obese, with a history of type II diabetes, abnormal thyroid findings, iron deficiency anemia, arthralgias, and fatigue. *Id.* at 30-31.

Petitioner's medical records reveal that she visited Dr. Jeffrey Howard, a cardiologist, in late 2009, after she complained of palpitations, dyspnea, and chest pain. Pet'r's Ex. 5 at 8. Dr. Howard interpreted Petitioner's echocardiogram as indicating that Petitioner had "concentric LV hypertrophy" and "minimal to mild mitral regurgitation," but his overall impression was that Petitioner's echocardiogram was normal and "no stress induced regional wall motion abnormalities" were detected. *Id*. at 10-11. For these and other reasons, Dr. Howard concluded further diagnostic testing was unwarranted. *Id* at 12.

Throughout 2010, Petitioner sought treatment at Healing Innovations and frequently had visits to address various medical issues including elevated blood pressure, heart palpitations, rapid heart beating, and/or chest pain or pressure. *See* Pet'r's Ex. 6 at 2-29; Pet'r's Ex. 12 at 3. Additionally, Petitioner went to the hospital emergency room for dizziness and chest pain on June

1, 2010 and June 9, 2010. Pet'r's Ex. 13 at 90-96, 128-33. At both visits, Petitioner received an electrocardiogram (ECG). Notably, Petitioner's ECG on June 9, 2010 was abnormal as compared to her June 1, 2010 ECG, an abnormality that her treating physician believed indicated "possible anterior infarct." Dec. at 6 (quoting Pet'r's Ex 13 at 98, 128).

Moreover, in early 2011, after Petitioner underwent left knee surgery and suffered an episode of laryngospasm, *id*. (citations omitted), she complained to Dr. Roger S. Blair of shortness of breath and heart palpitations. *Id*. (citing Pet'r's Ex. 12). A month later, Petitioner also underwent a neurological evaluation from Dr. Hung Huy Nguyen. *Id.* (citing Pet'r's Ex. 11 at 2-4). During that visit, Petitioner reported family history of myocardial infarction, but tests showed Petitioner's heart had regular rhythm and no murmur. *Id*.

Against this backdrop, on October 13, 2011, Petitioner received the influenza vaccine at the Walgreens pharmacy, located at 2253 Central Drive, Bedford, Texas. Pet. ¶ 1 (citing Pet'r's Ex. 21 at 19.[4] Six days later, Petitioner experienced sudden chest pain after sitting down from "rushing around the house for towels to clean up [a water leak]." Pet'r's Ex. 24 at 195. An ambulance was called; while en route to the hospital, Petitioner suffered ventricular fibrillation. *Id.* Petitioner was admitted to Texas Health Harris Methodist Hospital Hurst-Euless-Bedford for ventricular fibrillation cardiac arrest. *Id*. at 170. On the same day she was admitted to the hospital, Petitioner consulted cardiologist, Dr. Srinivas Paranandi. Pet'r's Ex. 9 at 13-20. She informed Dr. Paranandi that immediately prior to her ventricular fibrillation, she was "emotionally quite upset" by the events surrounding a water leak. *Id*. at 13. She later explained to other treating physicians that immediately prior to her ventricular fibrillation she had an "emotional argument

[4] Although not mentioned in the Special Master's Decision, the Court notes that Petitioner received flu vaccines on September 25, 2009, and November 2, 2010, without incident. Pet'r's Ex. 6 at 36, 41-42.

with her husband" and was "rushing around the house for towels" while "helping her husband with repair of some bathroom parts, where there was significant leakage." Pet'r's Ex. 15 at 3, 17; Pet'r's Ex. 19 at 12, 20, 29, 38, 57, 72; Pet'r's Ex. 22 at 76, 98, 104, 123; Pet'r's Ex. 24 at 195. It was during these events that Petitioner began to experience tightness in her chest, which she described as feeling like "an expanding balloon in her chest." Pet'r's Ex. 9 at 13

Petitioner also told Dr. Paranandi that during a cardiac assessment two years prior, Petitioner was told that one of her heart valves "may not be closing well." *Id*. at 14. Dr. Paranandi also assessed that Petitioner's diagnostic testing on the day of her cardiac episode showed the following:

- "[c]hest x-ray showed some patchy infiltrates, possibly due to aspiration,"
- "[c]ardiac enzymes are negative for myocardial injury so far,"
- "[e]chocardiogram showed ejection fraction of 70 percent and moderate left ventricular hypertrophy,"
- "EKG was nonacute and no significant ST segment deviations were noted,"
- "CT angiography study . . . was nonacute," and
- no significant valvular or wall-motion abnormalities.

Id. at 14, 16. Petitioner underwent a diagnostic cardiac catheterization which yielded unremarkable results. Pet'r's Exs. 2 at 20; 9 at 18-23; 24 at 209-213. Upon evaluating coronary risk factors, Dr. Paranandi noted Petitioner as being morbidly obese with a history of hypertension, hyperglycemia, and hyperlipidemia but did not note that Petitioner had a prior documented history of coronary disease or peripheral vascular disease. Pet'r's Ex. 9 at 14. Ultimately, Dr. Paranandi was uncertain as to the exact reason for Petitioner's cardiac event, in part, because Petitioner had normal left ventricular function. *Id*. at 16.

Petitioner was referred to Dr. Scott L. Greenberg, who also noted that the cause of Petitioner's ventricular fibrillation was unclear but that Petitioner "d[id] not have significant electrolyte disorder, cardiomyopathy, or obstructive coronary artery disease." Pet'r's Ex. 24 at

207. Additionally, Dr. Greenberg indicated that Petitioner had "mild elevation of her troponin," which he attributed to the rapid heartbeat and cardiac arrest, "as opposed to a primary myocardial infarction." *Id*. On Dr. Greenberg's recommendation, Petitioner had a defibrillator implanted. Pet'r's Ex. 9 at 21.

On October 21, 2011, Petitioner was discharged from the hospital in stable condition. Pet'r's Ex. 2 at 20. Throughout 2011 and 2012, Petitioner met with Drs. Paranandi and Greenberg for various follow-up appointments. Notably on a December 5, 2011 visit, Dr. Paranandi indicated as part of Petitioner's history that "[s]he had a[n] emotional argument with her husband prior to [cardiac arrest] and it was felt that she probably had a coronary spasm event, since there was a small area of mild focal disease in the mid anterior region." Pet'r's Exs. 15 at 3; 19 at 57.

Additionally, in many of these appointments, Petitioner complained of chest pain related to her implanted defibrillator, as well as various other ailments. Pet'r's Exs. 9 at 3; 15 at 6; 19 at 57. But after each of these appointments, her treating physicians concluded the defibrillator was functioning well and Petitioner's heart condition was stable. *See e.g.*, Pet'r's Exs. 14 at 2-3; 15 at 3-4; 19 at 40. However, Dr. Paranandi, recommended that Petitioner should be assessed for obstructive sleep apnea. Pet'r's Exs. 15 at 4; 19 at 40.

On April 6, 2012, Petitioner had an ECG performed during a visit to the emergency room which showed that Petitioner had poor R-wave progress across the precordium; and, "[c]ompared with prior ECG, T wave amplitude in anterior leads has decreased, NS T wave changes laterally no longer present." Pet'r's Ex. 22 at 134. On April 10, 2012, Petitioner was evaluated by Dr. Paranandi who found that Petitioner was "positive for chest pain, palpitations and leg swelling," Pet'r's Ex. 19 at 31, and that Petitioner's ECG showed "sinus rhythm, no acute changes or prior infarctions, left posterior fascicular block pattern." *Id.* at 28. Dr. Paranandi reiterated his

recommendation that Petitioner needed an assessment for obstructive sleep apnea but again concluded that Petitioner's heart condition was stable. *Id*. at 29.

On June 12, 2012, Petitioner met with Dr. Paranandi again and reported that she had been experiencing mild chronic shortness of breath and occasional brief palpitations and emotional distress for various reasons. Pet'r's Ex. 16 at 2. During this visit, Petitioner took another ECG which showed "sinus rhythm, poor R-wave progression through precordial leads, and no acute changes or definite prior infarction." *Id*. Petitioner's follow-up visit was otherwise unremarkable. *Id*. at 5.

On October 24, 2012, after participating in a nocturnal polysomnogram study and a home sleep test, Petitioner was diagnosed with obstructive sleep apnea. Pet'r's Ex. 17 at 8-13.

On July 19, 2013, Petitioner again met with Dr. Paranandi to discuss a June 29, 2013 ECG which showed that Petitioner had mild left ventricular hypertrophy with normal chamber dimensions. Pet'r's Ex. 22 at 87-88.

On June 5, 2014, after Petitioner had brought this action, Petitioner visited Dr. Stevan Cordas, D.O, M.P.H. Pet'r's Ex. 30 at 1-2. Petitioner reported "that in October 2011 she had [been] incorrectly provided influenza injection at Walgreens and then she developed a flu-like syndrome almost immediately . . ." *Id*. at 1. Dr. Cordas was aware that Petitioner was pursuing a vaccine-injury related claim. *Id*. at 1-2. Dr. Cordas stated, "[n]o symptoms typical of anaphylactic or anaphylactoid reactions related to the vaccine, so I cannot directly link the cardiac arrest to the flu shot." *Id*. at 2.

On November 10, 2014, Petitioner visited Dr. Paranandi again for an outpatient follow-up and reported that she went to the emergency room on September 27, 2014 for chest pain. Pet'r's Ex. 45 at 65-72. However, testing revealed that Petitioner's heart was stable. *Id*.

Throughout 2015 to 2018, Petitioner continued visiting Dr. Paranandi for follow-ups and defibrillator evaluations. *See generally* Pet'r's Exs. 44; Ex. 45 at 168-75, 181-201, 355-62. Overall, Petitioner was stable from a cardiovascular standpoint. Pet'r's Exs. 44 at 122; Ex. 45 at 141. During that period, Petitioner received a stress test with results that were considered unremarkable and an ECG that showed mild left ventricular hypertrophy with ejection fraction of 60-65% and grade II diastolic dysfunction. Pet'r's Ex. 44 at 96.

In sum, the undisputed record shows that following her 2011 cardiac event, Petitioner experienced numerous ailments, but her heart function remained stable.

II. Expert Opinions

Given that Petitioner's medical records showed considerable risk factors, the Special Master informed Petitioner that it would be difficult for her to prove causation without retaining an expert to provide a legally probable theory of causation. *See* ECF Nos. 7, 11. The Special Master reviewed a total of eleven expert reports that were filed by four different cardiology experts over a span of six years.

A. Dr. Waugh's Initial Opinion

Petitioner initially filed a report by Dr. Robert A. Waugh, who exchanged views with Respondent's initial expert, Dr. Sperling. *See generally* Pet'r's Ex. 25 (Waugh initial report) (ECF No. 18-1); Ex. 29 (Waugh First Supplement) (ECF No. 32-1);[5] Ex. 35 (Waugh Second Supplement) (ECF No. 38-1). In his initial report, Dr. Waugh opined that "[g]iven the proximate temporal sequence of events . . . and an episode of significant emotional distress shortly thereafter . . . in combination with the absence of significant coronary artery disease by coronary angiography

[5] Dr. Waugh's unsigned supplemental opinion was initially filed as Petitioner's Ex. 27, and later refiled with a signature as Petitioner's Ex. 29.

. . .it is *plausible* that [petitioner] suffered an episode of coronary spasm . . . ." Pet'r's Ex. 25 at 3 (emphasis added). However, Dr. Waugh could not tie the vaccination to his theorized coronary spasm because "[t]he exact pathophysiologic sequence at the cellular level between vaccination, coronary artery spasm,[and Petitioner's] emotional distress remains to be elucidated. *Id*.

The Special Master found Dr. Waugh's initial opinion inadequate and ordered Petitioner to file a supplemental opinion comporting with the *Althen* factors and specifically addressing: (1) "a medical theory of how the flu vaccine causes cardiovascular spasm;" (2) "a medical theory explaining why six days [would be] an appropriate onset interval to link cardiovascular spasm in a vaccine recipient;" and (3) explaining the basis for his opinion that the flu vaccine caused Petitioner's cardiovascular spasm as opposed to her multitude of cardiac risk factors (inter alia morbid obesity, diabetes, hypertension, hypothyroidism, hyperlipidemia, and a family history of heart disease). Order filed August 22, 2014 (ECF No. 20).

In his first supplement to his report, Dr. Waugh attempted to further elucidate on "a plausible mechanism to explain how a vaccine could have caused the cardiac event [Petitioner] suffered." Pet'r's Ex. 29 at 2. To develop a plausible theory, Dr. Waugh relied in significant part on a study by Lanza et al., which discussed vaccine-induced changes in platelet activity leading to a transient increase in the risk of cardiovascular events. Pet'r's Ex. 29 (citing Pet'r's Ex. 28 (Gaetano A. Lanza et al., Inflammation-Related Effects of Adjuvant Influenza A Vaccination on Platelet Activation and Cardiac Autonomic Function, 269 J. INTERNAL MEDICINE 118 (2011) (Lanza et al.) (ECF No. 29-2)).

The Lanza study examined twenty-eight patients with type II diabetes over the course of three days. Lanza et al. at 1-2. On day one, patients underwent a twenty-four-hour ambulatory electrocardiogram monitoring and had a blood sample collected. *Id*. at 1-2. On day two, the

patients were administered an influenza A vaccination. *Id*. On day three, patients had a second twenty-four-hour ECG recording. *Id*. Additional blood samples were drawn twenty-four and forty-eight hours after the vaccination. *Id*. C-reactive protein, interleukin-6 levels, monocyte-platelet aggregates and monocyte/platelet receptor expression were measured. *Id*. at 1. A control group of twelve patients underwent the same testing but did not receive any vaccination. *Id*. at 3. The Lanza authors concluded that:

> influenza A vaccination in patients with type II diabetes induces, together with the expected inflammatory reaction, an increase in platelet activation and a cardiac sympathovagal imbalance. Overall, the vaccine-induced changes in platelet activity and autonomic nervous activity may transiently increase the risk of cardiovascular events in vaccinated patients.

Id. at 7.

Dr. Waugh opined that "[t]his suggests a pathophysiological link between inflammation and cardiac autonomic dysregulation which, in turn, increases the risk of cardiovascular events." Pet'r's Ex. 29 at 2. Dr. Waugh readily acknowledged that Petitioner had ongoing cardiac risk factors, but stated she had no notable findings on angiography or ventriculography following her cardiac event. *Id*. For these reasons, he concluded that a transient heart rate variability brought on by inflammation "to a reasonable degree of medical probability, the flu vaccine was a substantial factor in bringing about [Petitioner's] cardiac event . . . ." *Id*.

The Special Master ordered Petitioner to file a second supplemental opinion from Dr. Waugh explaining: "(1) how the Lanza article, [showing] inflammation up to two days after [flu] vaccination, supports the timing of [P]etitioner's alleged reaction six days after [flu] vaccination; and, (2) how the [article's] authors' finding of increased risk of a clot up to two days [after] vaccination relates to [P]etitioner's case, [since P]etitioner had atrial fibrillation, not a clot, six days after [receiving the flu vaccine]. Order filed February 23, 2015 (ECF No. 30).

In his second supplemental report, Dr. Waugh clarified that he was relying on the Lanza study's findings with respect to sympathovagal imbalance. Pet'r's Ex. 35. Dr. Waugh explained that the Lanza study found that inflammation as indicated by increased C-reactive protein, effects heart rate variability, which in turn can lead to cardiac events. *Id*.

B. Dr. Sperling's Responsive Opinion

Respondent provided a competing opinion from Dr. Laurence S. Sperling, who believed it was more likely that Petitioner's ventricular fibrillation arrest "was due to uncharacteristic physical exertion and profound emotional distress." Resp't's Ex. A at 5 (ECF No. 41). Dr. Sperling believed that Petitioner's pre-existing conditions, such as "her morbid obesity, type II diabetes and hypertension already predisposed her to having [an] acute cardiovascular event and underlying endothelial dysfunction." *Id*. at 3. Dr. Sperling opined that these risk factors coupled with "[t]he elevated pulse secondary to physical exertion and emotional distress provided an extra cardiac burden that may have resulted in coronary artery spasm and then an unstable cardiac rhythm." *Id*.

Dr. Sperling also took issue with Dr. Waugh's reliance on the Lanza article because according to Dr. Sperling, "the overwhelming preponderance of scientific data supports the influenza vaccine as being cardioprotective." *Id.* at 4. Dr. Sperling cited two studies that involved over 26,000 patients in total, showing no adverse cardiovascular effect following a flu vaccination. *Id.* Dr. Sperling highlighted that the Udell article noted a significant decrease in cardiovascular events in patients that were considered of high cardiovascular risk and that the Smeeth article concluded that the "mild transient inflammation induced by vaccination does not appear to translate into a detectable increase in the risk of vascular events." *Id*. (citing Resp't's Ex. C (Jacob A. Udell et al., *Association Between Influenza Vaccination and Cardiovascular Outcomes in High-Risk Patients: A Meta-Analysis*, 310 (16) JAMA 1711 (2013)) (Udell et al.)) (ECF No. 41-3);

Resp't's Ex. D (Liam Smeeth et al., *Risk of Myocardial Infraction and Stroke After Acute Infection or Vaccination*, 351 N. ENG. J. MED. 2611 (2004) (Smeeth et al.)) (ECF No. 41-4). For these reasons, Dr. Sperling concluded that it was highly unlikely that her cardiac arrest was related to her vaccine. Resp't's Ex. A at 5.

C. Dr. Waugh's Response

Dr. Waugh retorted that he believed that Dr. Sperling's theory placed too much weight on Petitioner's pre-existing conditions because "[a]lthough she has multiple *putative* cardiac risk factors, none has proved to have caused her any harm." Pet'r's Ex. 36 at 1 (ECF No. 44-1). Dr Waugh believed that "there was nothing wrong with [Petitioner's] heart," and therefore deduced that on the day of her cardiac event, "the only variable not previously present was the influenza vaccine . . . ." *Id*. at 1-2. Dr. Waugh further criticized Dr. Sperling's reliance on articles that found flu vaccines to be cardiovascular protection overly generalized as to apply to Petitioner's specific factors in this case. *Id*. at 2.

D. Dr. Sperling's Second Response

Dr. Sperling responded to these criticisms by acknowledging that "a definitive etiology in regard to [Petitioner's] acute cardiovascular event is not possible to determine." Resp't's Ex. E at 1 (ECF No. 50-1). However, Dr. Sperling noted that there is evidence in Petitioner's medical records that she experienced stress shortly before the onset of her cardiac event and the Sharkey article, originally cited by Dr. Waugh, also found "it is not understood why a specific stressful event will on one occasion trigger this condition whereas at another time a similar circumstance (even more stressful) does not." *Id*. at 4 (citing Pet'r's Ex. 38 (Scott W. Sharkey, John R. Lesser & Barry J. Maron, *Cardiology Patient Page: Takotsubo (Stress) Cardiomyopathy*, 124:18 CIRCULATION e460 (2011) at 3) (Sharkey, Lesser & Maron) (ECF No. 44-3)) (quotations

omitted). Accordingly, Dr. Sperling maintained that the combination of stress and pre-existing conditions is still the most likely cause of Petitioner's cardiac event. Resp't's Ex. E at 3-4.

An entitlement hearing was subsequently set, but then cancelled due to Dr. Waugh's retirement. (ECF Nos. 51-53.) Petitioner was ordered to file a report by a different expert or dismiss the case. Order, dated June 22, 2017 (ECF No. 54). However, Petitioner's counsel (Franklin John Caldwell, Jr.) withdrew from the case before any expert report was filed. (ECF Nos. 54-61.) Subsequently, both experts ceased participating in the case and additional cardiology experts, Dr. Robert M. Stark (for Petitioner) and Dr. Shane R. LaRue (for Respondent), were retained to offer further opinions and to be available for a potential entitlement hearing. Pet'r's Notice of Filing (ECF No. 69) (announcing Dr. Stark's opinion); Resp't's Notice of Filing (ECF No. 72) (announcing Dr. LaRue's opinion). On September 12, 2017, Special Master Millman held a status conference with Respondent and Petitioner, now proceeding pro se. (ECF No. 63). Petitioner indicated that she was seeking another attorney, but also indicated that she wished to change her theory of the case. *Id.* Petitioner wished to allege vaccine-caused peripheral neuropathy, Guillain-Barre syndrome, and positive findings of cytomegalovirus and Epstein Barr virus. *Id.* Special Master Millman indicated that additional medical records substantiating these allegations would be needed but that Petitioner should first determine whether she will proceed with different counsel. *Id.*

E. Dr. Stark's Initial Opinion

Dr. Stark's basis for opining in the case differed from Dr. Waugh's opinion. Unlike Dr. Waugh, who explicitly rejected increased platelet activation as the cause of Petitioner's cardiac arrest, Dr. Stark theorized that Petitioner's flu vaccination triggered an antigen-antibody reaction that inflamed the arteries and could have "cause[d] the platelets in smaller blood vessels to clump

together and stick to the vessel wall," which in turn led to Petitioner's cardiac arrest. Pet'r's Ex. 39 at 2-3 (ECF No. 69-1). Dr. Stark ruled out other causes such as artery disease and any pre-existing arrhythmogenic focus based on the Petitioner's negative stress test, normal cardiac catherization, and lack of any previous cardiac problems (arrythmias, coronary artery lesions, fainting). *Id*. Like Dr. Waugh, Dr. Stark concluded that the flu vaccination caused Petitioner's cardiac arrest because it was "[n]ot until [Petitioner] received a flu vaccine (six days before) did she have her first episode of chest pain, collapse and cardiac arrest." *Id*. at 2.

F. Dr. LaRue's Responsive Opinion

Dr. LaRue filed reports responsive to both Dr. Stark and Dr. Waugh. Resp't's Ex. H (ECF No. 72-1). Like Dr. Sperling, Dr. LaRue opined that "it is far more likely that [Petitioner] experienced [ventricular fibrillization] arrest due to her underlying risk and acute trigger . . . " Resp't's Ex. H at 5. To support this conclusion, he noted that both Petitioner's pre- and post-cardiac arrest electrocardiograms indicated poor R-wave progression in the precordial leads, and this suggests that Petitioner has left ventricular hypertrophy (LVH) or an abnormality in the mid-anterior wall of her left ventricle. *Id*. at 4. Dr. LaRue additionally emphasized that Petitioner's ECG indeed documented that Petitioner has LVH and "LVH has a well-established association with ventricular arrhythmias." *Id*. He cited to the McClenaghan and Haider articles which found hypertensive individuals with LVH experienced higher frequencies of ventricular premature contractions and that LVH was a risk factor for sudden death, respectively. *Id*. (citing Resp't's Ex. K (James M. McLenachan et al., *Ventricular Arrythmias in Patients with Hypertensive Ventricular Hypertrophy*, 317 N. ENGLAND J. MED. 787 (1987))) (McLenachan et al.) (ECF No. 75-2); Resp't's Ex. L (Agha Haider et al., *Increased Left Ventricular Mass and Hypertrophy are Associated with Increased Risk for Sudden Death*, 32:5 J. AM. COLLEGE Cardiology 1454

(1998)) (Haider et al.) (ECF No. 75-3). Additionally, Dr. LaRue opined, citing to the Gami study, that Petitioner's obstructive sleep apnea increased her risk for ventricular arrythmia and sudden cardiac death. Resp't's Ex. H at 4-5 (citing Resp't's Ex. M (Apoor S. Gami et al., *Obstructive Sleep Apnea and the Risk of Sudden Cardiac Death: A Longitudinal Study of 10,701 Adults*, 62:7 J. AM. COLLEGE CARDIOLOGY 610 (2013)) (Gami et al.) (ECF No. 75-4). Lastly, he opined that the emotional and physical stress significantly contributed to Petitioner's cardiac event. Resp't's Ex. H at 5. Dr. LaRue cited to the Lampert study that found elevated levels of anger and anxiety and mild-to-moderate physical activity significantly preceded defibrillator shocks. *Id*. (citing Respondent's Ex. N (Rachel Lampert et al., *Emotional and Physical Precipitants of Ventricular Arrythmia*, 106 CIRCULATION 1800 (2002) (Lampert) (ECF No. 75-5)).

Dr. LaRue suggested that Dr. Waugh's reports contained contradictions and further emphasized that Dr. Waugh had previously opined that coronary artery spasm and emotional stress, both unrelated to flu vaccine, explained ventricular arrhythmias. Resp't's Ex. H. at 6. Dr. LaRue also explained that the "influenza vaccine has been studied in numerous trials, in hundreds of thousands of people, and no reports of associated ventricular arrythmias have been made." *Id*. at 7 (citing Respondent's Ex. P (Rohit S. Loomba et al., *Influenza Vaccination and Cardiovascular Morbidity and Mortality: Analysis of 292 383 Patients*, 17 J. CARDIOVASCULAR & THERAPEUTICS 277 (2012)) (Loomba et al.) (ECF No. 75-7)). Dr. LaRue also disagreed with Dr. Waugh's opinion that "there was nothing wrong with [Petitioner's] heart." Resp't's Ex. H at 8. Addressing the medical record, Dr. LaRue noted that Petitioner's ECG demonstrated mild LVH and that Petitioner "experienced at least 13 episodes of ventricular tachycardia or non-sustained ventricular tachycardia . . . over the 11 months immediately following her arrest . . . " *Id*. The continued nature of these arrhythmias undermines Respondent's theory that transitory

inflammation caused Petitioner's arrythmia which led to her cardiac arrest. *Id*.

Dr. LaRue also rebutted Dr. Stark's opinion, emphasizing that Petitioner's cardiac catherization report did not "suggest [Petitioner] had an acute myocardial infarction of a small vessel such as slow coronary flow or a vessel that was occluded." *Id*. at 4. He again pointed to Petitioner's poor R-wave progression and post arrest ventricular arrhythmias which he believed indicated "[Petitioner] may well have had an arrhythmogenic focus that had not yet manifest, and finally did so in the setting of the catecholamine surge of her stressful situation." *Id*. at 9. Further, Dr. LaRue relied on the Posthouwer study, which showed C-reactive protein and thrombin activation to return to baseline at day four and five post-vaccination, to rule out the possibility of Petitioner's cardiac arrest being caused by clotting due to vaccine-induced inflammation. *Id*. at 8-9 (citing Resp't's Ex. R (Dirk Posthouwer et al., *Influenza and Pneumococcal Vaccination as a Model to Assess C-Reactive Protein Response to Mild Inflammation*, 23 VACCINE 362 (2004) (Posthouwer et al.) (ECF No. 75-9)).

Ultimately, Dr. LaRue concluded that, considering the lack of reported cases relating flu vaccine to ventricular arrhythmias or sudden cardiac death, Petitioner's flu vaccine, "more likely than not," did not contribute to Petitioner's cardiac arrest. Resp't's Ex. H at 10. Conversely, there substantial support showing that cardiac arrest can be caused by the combination of underlying hypertensive heart disease and obstructive sleep apnea. *Id*.

G. <u>Dr. Stark's Response</u>

Dr. Stark responded refuting Dr. LaRue's suggestion that Petitioner's sleep apnea was a causal factor because "[s]leep apnea patients face their greatest risk for arrhythmia when their blood oxygen levels decline to low levels during night time sleep;" whereas, Petitioner had her cardiac arrest when she was not asleep and during the day. Pet'r's Ex. 43 at 1-2 (ECF No. 74-1).

Dr. Stark also refuted Dr. LaRue's suggestion that hypertension played a rule in Petitioner's cardiac event because "[v]irtually all patients with hypertension have some degree of left ventricular hypertrophy;" but, according to Dr. Stark, Petitioner's mild left ventricular hypertrophy "is a negligible contributor to potential ventricular fibrillation or cardiac arrest." *Id*. at 2. He continued that "poor R-wave progression . . . can be, and is, a normal variant in an individual's EKG." *Id*. (internal quotations omitted). Regarding Petitioner's post-vaccination arrhythmias, Dr. Stark posited that these arrythmias could indicate that there was an arrhythmogenic focus, but most likely, the focus came from the area that was damaged when Petitioner had her cardiac arrest and thus could not disprove that the flu vaccine caused the arrythmia which lead to Petitioner's cardiac arrest. *Id*. at 3.

H. Dr. LaRue's Second Response

In his response, Dr. LaRue noted that there is an increased risk of obstructive sleep apnea induced arrythmias during the daytime due to the "increase in sympathetic drive," although the greatest risk remained during nighttime. Resp't's Ex. S at 1 (ECF No. 77-1). He also disagreed with Dr. Stark's suggestion that mild LVH has negligible arrhythmic risk, because neither the McLenachan trial or Haider study, which found higher incidence of ventricular arrythmias to be associated with LVH, attributed any significance to LVH severity. *Id*. at 1-2. Regarding Petitioner's post-arrest ventricular tachycardia, Dr. LaRue disagreed with Dr. Stark that the focus originated from the area damaged from Petitioner's cardiac arrest because such damage would be evident in an electrocardiogram, but Petitioner's ECG both pre- and post-arrest were essentially undifferentiated. *Id*. at 3. Regarding inflammation, Dr. LaRue agreed with Dr. Stark that inflammatory mediators exert an effect on vascular endothelium; but, in this case, there is no evidence indicating that Petitioner experienced significant inflammation six days post-vaccination.

Id. at 2. Regarding clotting, Dr. LaRue agreed that many measures of clotting ability exist; however, "[t]hrombin is required both for the initiation and the propagation of the clotting cascade and thus elevation in prothrombin fragment is seen in a hypercoagulable state," showing that the Posthouwer article is indeed relevant to this case. *Id*. at 2-3 (footnote omitted).

I. Dr. Stark's Final Response

On September 23, 2019, Petitioner filed a Motion for Decision on the Record. (ECF No. 92). On February 5, 2020, Petitioner filed a limited second supplemental expert report from Dr. Stark. *See* Pet'r's Ex. 54 (ECF No. 96-1). In his final response, Dr. Stark opined that "[t]he absence of significant coronary disease makes the alternative of coronary inflammation far more likely" and that Petitioner's known diabetes predisposes her to small vessel inflammation and spasm. *Id*. at 1. Dr. Stark emphasized that systemic inflammation from recent flu immunization can cause a cardiac event, where the mechanism is "virtually identical to that for influenza infection." *Id*. Again, Dr. Stark highlighted the Lanza study, showing that for diabetic patients, there were "significant rises in inflammatory markers as well as platelet activation and adrenergic activation which are known to predispose to heart attack." *Id*. at 2. He concluded that he believed to a "reasonable degree of medical certainty" that Petitioner's cardiac arrest was caused by systemic inflammation from her flu vaccine. *Id.*

III. Special Master's Decision

On June 4, 2020, the Special Master issued his Decision denying entitlement. (ECF No. 104.) Based on the medical records and expert opinions, the Special Master found that Petitioner had failed to meet the requirements of *Althen* prongs one and two. With respect to prong one, the Special Master found that neither Dr. Waugh's nor Dr. Stark's theories of causation were legally plausible because neither expert persuasively explained how inflammation from the vaccine, and

specifically the brand Fluvirin, can lead to ventricular fibrillation and/or cardiac arrest. Dec. at 22-28.

With respect to *Althen* prong two, the Special Master held that Petitioner had failed to show, by preponderance of the evidence, that the flu vaccine caused Petitioner's ventricular fibrillation. Dec. at 28-31. The Special Master explained that none of Petitioner's treating physicians noted any concerns of inflammation as a factor for petitioner's ventricular fibrillation. Dec. at 28. Moreover, Petitioner's experts were unable to consistently articulate what effect inflammation had on Petitioner's heart. Dec. at 29. Conversely, the Special Master found that Petitioner's contemporaneous medical records supported Respondent's theory that Petitioner's ventricular fibrillation was caused by a combination of pre-existing risk factors and stress. Dec. at 30-31.

On July 6, 2020, Petitioner filed a Motion for Review of the Special Master's Decision denying her claim pursuant to Rule 23 of the Vaccine Rules of the United States Court of Federal Claims (Vaccine Rules). (ECF No. 106). Petitioner argues that the Special Master's determinations with regard to *Althen* prongs one and two were arbitrary and capricious. *Id*. Under *Althen* prong one, Petitioner takes issue with the probative weight the Special Master assigned to the Lanza study and the Fluzone post-marketing information. Pet'r's Br. at 16-17; Pet'r's Reply Br. at 2-3 (ECF No. 115). She argues that her position is supported by *Halverson v. Sec'y of Health & Human Servs.*, where a special master found entitlement for cardiac injuries caused by a Fluzone vaccination. Pet'r's Br. at 17 (citing *Halverson v. Sec'y of Health & Human Servs.*, No. 15-227V, 2020 WL 992588, *21 (Fed. Cl. Spec. Mstr. Feb. 4, 2020)); Pet'r's Reply Br. at 1-2. Under *Althen* prong two, Petitioner argues that the Special Master erroneously interpreted the medical records to suggest that Dr. Paranandi opined at a medical visit that her ventricular fibrillation was due to

stress. Pet'r's Br. at 6-7. She also argues that the Special Master subjected her to an elevated burden of proof because "[t]here is no requirement under *Althen* prong 2 for Petitioner to demonstrate results from tests that are not routinely administered . . . " Pet'r's Br. at 7. She argues that the causal theories put forth by her experts are sufficient to meet her burden of proof under *Althen* prong two. Pet'r's Br. at 9-14, 18-19.

As explained below, these contentions are without merit.

APPLICABLE STANDARD OF REVIEW

The National Childhood Vaccine Injury Act of 1986 (Vaccine Act) created the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa–10 *et seq.*, to provide compensation to people found to be injured by certain vaccines. Congress established the Vaccine Act after lawsuits against vaccine manufacturers and healthcare providers threatened to cause vaccine shortages and reduce vaccination rates. *See Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 227-28 (2011). Petitions alleging injuries caused by a vaccine must be filed in the United States Court of Federal Claims, and a special master initially reviews and issues a decision on the petition. *Id*. at 228 (citing 42 U.S.C. § 300aa–11(a)(1).

Under the Vaccine Act, the United States Court of Federal Claims reviews the special master's decision upon the filing of a Motion for Review of Decision of Special Master. 42 U.S.C. § 300aa–12(e). Upon such review of the special master's decision, the Court may:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
>
> (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2); *accord* Vaccine Rule 27(c). The standards set forth in 42 U.S.C. § 300aa-12(e)(2)(B), "vary in application as well as degree of deference" as each "standard applies to a different aspect of the judgment." *Munn v. Sec'y of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992). "Thus, the [United States Court of Federal Claims] judge reviews the special master's decision essentially for legal error or factual arbitrariness." *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1574 (Fed. Cir. 1993).

"[S]pecial masters have broad discretion to weigh evidence and make factual determinations." *Dougherty v. Sec'y of Health & Human Servs*., 141 Fed. Cl. 223, 229 (2018). When reviewing the special master's factual findings, the court does "not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder." *Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011). This Court should not "second guess the Special Master[']s fact-intensive conclusions particularly in cases in which the medical evidence of causation is in dispute." *Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010) (quoting *Hodges v. Sec'y of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993)) (quotations omitted).

DISCUSSION

Under the Vaccine Act, Petitioner may demonstrate eligibility for an award in two ways. *See Munn v. Sec'y of Health & Human Servs.,* 970 F.2d 863, 865 (Fed.Cir.1992). Petitioner may either show that she suffered an injury listed on the Vaccine Injury Table within the requisite time period, in which causation is presumed (table injury), or she may demonstrate that her condition

was caused-in-fact by the flu vaccine (off-table injury). *Capizzano*, 440 F.3d at 1320-21 (citing *Munn*, 970 F.2d at 865; 42 U.S.C. §§ 300aa-13(a)(1), -11(c)(1)(C)(ii)(I)).

It is undisputed that neither ventricular fibrillation nor cardiac arrest is a presumptive injury following receipt of the flu vaccine. *See* 42 U.S.C. § 300aa-14(a) (Vaccine Injury Table) *see also* Resp't's Br. at 11. Therefore, Petitioner alleges is an off-table injury, and Petitioner must prove by a preponderance of the evidence that her vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). In making this showing "that the vaccination brought about her injury," Petitioner must provide:

> (1) a medical theory causally connecting the vaccination and the injury,
>
> (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury, and
>
> (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen, 418 F.3d at 1278; *see Boatmon v. Sec'y of Health & Human Servs.*, 941 F.3d 1351, 1354-55 (Fed. Cir. 2019). A petitioner must prove all three *Althen* prongs by a preponderance of the evidence. *See Boatmon*, 941 F.3d at 1355; *Althen*, 418 F.3d at 1278. "Once a petitioner establishes a prima facie case, the government then bears the burden of establishing alternative causation by a preponderance of the evidence." *Cedillo,* 617 F.3d at 1335 (citation omitted); *see Althen,* 418 F.3d at 1278 (Petitioner is recovers unless Defendant shows "also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine") (quotation omitted).

However, if the petitioner fails to establish a prima facie case, then, of course, this burden does not shift to respondent. *See Deribeaux v. Sec'y of Health & Human Servs.*, 105 Fed. Cl. 583, 587 (2012), *aff'd*, 717 F.3d 1363 (Fed. Cir. 2013); *see also Doe v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1358 (Fed. Cir. 2010). Nevertheless, regardless of whether the burden of proof

ever shifts to the respondent, the special master may consider such evidence presented by the respondent in determining whether the petitioner has established a prima facie case, as the special master is to consider the record as a whole in determining causation. *See Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373, 1380 (Fed. Cir. 2012) (citing *Doe*, 601 F.3d at 1356-58; *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1353 (Fed. Cir. 2008); *Shyface*, 165 F.3d at 1352).

I. *Althen* Prong One

"Under the first [*Althen*] prong, a petitioner must demonstrate that the vaccine at issue can cause the injury alleged." *Greene v. Sec'y of Health & Human Servs.*, 146 Fed. Cl. 655, 663 (2020) (citing *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006)). To make this showing, "a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be 'legally probable, not medically or scientifically certain.'" *Broekelschen v. Sec'y of Heatlh & Human Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010) (quoting *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548–49 (Fed. Cir. 1994)).

Petitioner's experts proposed two different avenues by which inflammation could theoretically result in cardiac arrest. Dr. Waugh suggested that inflammation from a vaccination can destabilize cardiac autonomic function leading to an arrhythmia brought on by a "chemical-electrical instability" in the heart. Dec. at 13-17, 23-25. Petitioner's second expert, Dr. Stark, proposed that inflammation from a vaccination can lead to increased clotting (a prothrombotic state) leading to small blockages in microcirculation and cardiac arrest. *Id*. at 18, 21, 23. The Special Master found Petitioner failed to establish a legally probable theory that vaccine-induced inflammation can cause a cardiac arrest, and this Court concurs with the Special Master's findings.

Id. at 23-27.

A. Lanza Study

The Special Master found that neither Dr. Waugh's nor Dr. Stark's reliance on the Lanza study sufficiently supported their respective theories for multiple reasons. Dec. at 24. In grappling with the Lanza findings, the Special Master concluded that Lanza did not completely support Petitioner's theory that the flu vaccine can lead to a pro-thrombotic state. *Id*. Specifically, the Special Master noted that:

> the Lanza study failed to find any correlation between increased platelet activation (as measured by [monocyte-platelet aggregates]) and either [C-reactive protein] levels or [heart rate variability (HRV)] variables. [Lanza et al. at 4]. The authors explained that "[t]he increase in [monocyte-platelet aggregates], however, did not show any significant correlation with HRV changes, suggesting that the acute cell-mediated inflammatory response to viral vaccine did not result in appreciable effects on cardiac autonomic activity. Accordingly, no significant relation was found between HRV changes and platelet activation in this context. (*Id.* at 7.)

Dec. at 24. The Special Master also noted the study's shortcomings with respect to Dr. Waugh's "chemical-electrical instability" causation theory. Dec. at 24. Specifically, the Special Master noted that the Lanza study "shows only a correlation between elevated [C-reactive protein] and reduced [heart rate variability] and not a causal relationship." *Id.*

Notwithstanding these shortcomings, the Special Master explained, and this Court concurs, that he was troubled by the novelty of the study stating that the Lanza study was "intriguing as a piece of preliminary investigation" but fell "well short of supporting [P]etitioner's theory that post-vaccination inflammation can lead to ventricular fibrillation and/or cardiac arrest." *Id*. Moreover, the Special Master found that the Lanza study was not generalizable because the Lanza study included only twenty-eight patients. *Id*. at 25. The small scale of the Lanza study is particularly notable when juxtaposed with the larger scale studies that Respondent presented, finding that the flu vaccine is likely to be cardio protective. *See* Smeeth et al. (study involving 20,486 patients);

Udell et al. (study involving 6,735 patients); Loomba et al. (meta-analysis involving 292,383 patients). The Special Master stated while "[these] findings do not negate the Lanza study, . . . they do suggest . . . that the [Lanza study's] results should be interpreted with caution." Dec. at 25.

A special master's determination regarding the persuasiveness of expert testimony is afforded considerable deference. *Broekelschen*, 618 F.3d at 1347 ("[T]he special master's credibility findings, [concerning medical expert testimony,] 'are virtually unchallengeable on appeal'") (quoting *Lampe*, 219 F.3d at 1362). The Special Master was entitled to weigh the evidence from multiple sources and find that the novel Lanza study findings were less persuasive than multiple larger scale studies. *See Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1326 (Fed. Cir. 2010) ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them . . ."). Accordingly, this Court cannot say that the Special Master acted arbitrarily in favoring large scale studies over the small scale and novel Lanza study, especially when Petitioner's own experts relied on the Lanza study to support somewhat contradictory theories of causation.

B. Fluzone Post-Marketing Information

Likewise, the Special Master did not err in finding that Dr. Waugh's theory of causation was not sufficiently supported by post-marketing information from the high dose Fluzone brand of vaccine. To support his theory of causation, Dr. Stark relied on post-marketing information from the high dose Fluzone vaccine, as well as a clinical trial examining the immunogenicity of high dose vaccines to standard dose vaccines as evidence of "an antigen-antibody mediated inflammatory response[]" capable of acting on the endothelium of blood vessels. Pet'r's Ex. 43 at 2-3 (citing Pet'r's Exs. 55-57 (ECF No. 96)).

The Special Master provided several reasons for finding that this data was inapposite. First, the high dose Fluzone vaccine is a different vaccine from what Petitioner received, which was the Fluvirin brand vaccine. Dec. at 27. Additionally, the Special Master noted that the clinical trial examining the immunogenicity of high dose vaccines to standard dose vaccines was unpersuasive because although the authors concluded that the high dose flu vaccine induced a greater antibody response than the standard dose flu vaccine, there was no correlative increase in adverse reactions. Dec. at 27. The Special Master believed, and this Court agrees, that "[s]uch a conclusion would seem to weigh against any suggestion of a correlation between the antigen-antibody mediated inflammatory response . . ." *Id.*

This Court cannot find that the Special Master acted arbitrarily and capriciously in concluding the logical leap between the studies of high dose Fluzone, which Petitioner did not receive, and the lower dose Fluvirin, which Petitioner received, was too great. *See McCollum v. Sec'y of Health & Human Servs.*, 760 F. App'x 1003, 1008-09 (Fed. Cir. 2019) (affirming as permissible the special master's finding that a study involving a different vaccine than what the petitioner received was unpersuasive); *D'Tiole v. Sec'y of Health & Human Servs.*, 726 F. App'x. 809, 811 (Fed. Cir. 2018) (affirming special master's rejection of a medical theory, which was based largely upon literature concerning a vaccine with a distinct formulation and manufacturing process from the vaccine at issue).

C. *Halverson*

Finally, the Special Master did not err in concluding Petitioner's case was distinguishable from the petitioner in *Halverson*. In *Halverson*, another special master ruled that a high dose flu vaccine caused that petitioner's cardiac arrest and death. *Halverson*, 2020 WL 992588 at *32. As the Special Master noted, and this Court agrees, *Halverson* is distinguishable because the petitioner

in that case received a different vaccine and Petitioner's expert relied on studies involving the exact vaccine that the petitioner received. Dec. at 27 n.18. The Special Master found that the high dose vaccine in *Halverson* is materially different from the vaccine Petitioner received, because the high dose vaccine contained four times the amount of hemagglutinin, which is known to cause blood clotting, than the vaccine Petitioner received in this case. *Id*. It was not unreasonable for the Special Master to conclude that because of this difference in the amount of hemagglutinin, studies relating to high dose vaccines are not relevant for predicting the effects of low dose vaccines—such as the vaccine Petitioner received. Moreover, the Special Master is not bound by decisions of other special masters. *See Boatmon*, 941 F.3d at 1358-59 ("To the extent the Court of Federal Claims required that special masters cite and distinguish the decisions of other special masters, it was incorrect."); *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998), *aff'd*, 191 F.3d 1344 (Fed. Cir. 1999) ("Special masters are neither bound by their own decisions nor by cases from the Court of Federal Claims, except, of course, in the same case on remand.").

For these reasons, Petitioner has failed to show that the Special Master erred or acted in an arbitrary or capricious manner in finding that Petitioner did not meet the first *Althen* prong.

II. *Althen* Prong Two

The second prong of the *Althen* test requires the petitioner to demonstrate "a logical sequence of cause and effect showing that the vaccination was the reason for the injury" by a preponderance of the evidence. *Althen*, 418 F.3d at 1278 (citing *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)) (quotations omitted). In order to prevail, the petitioner must show "that the vaccine was not only a but-for cause of the injury but also a

substantial factor in bringing about the injury." *Althen*, 418 F.3d at 1278 (quoting *Shyface*, 165 F.3d at 1352-53). Testimony from treating physicians "is 'quite probative' since 'treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1375 (Fed. Cir. 2009) (quoting *Capizzano*, 440 F.3d at 1326); *see also Paluck v. Sec'y of Health & Human Servs.*, 786 F.3d 1373, 1385 (Fed. Cir. 2015) (finding "the special master erred in disregarding contemporaneous statements from [petitioners' minor child's] treating physicians regarding the cause of his neurodegeneration").

Petitioner argues that the Special Master erroneously interpreted Petitioner's medical records as not supporting Petitioner's theory of causation. Pet'r's Br. at 6-14. This Court disagrees. The Special Master did not err in interpreting Petitioner's medical records as supporting Respondent's rather than Petitioner's medical theory. As discussed above, Petitioner's experts theorized that the Fluvirin vaccine can induce various inflammatory responses which can lead to cardiac arrest. Dec. at 27. Consequently, Petitioner was required to prove by a preponderance of the evidence that one of her expert's theories actually occurred. *Broekelschen*, 618 F.3d at 1339 (holding the special master's determination that petitioner failed to provide a reliable medical explanation sufficiently linking the flu vaccine to petitioner's injury alleged was not arbitrary or capricious). Petitioner did not identify anything in her medical records to support any of her experts' various theories by a preponderance of the evidence. Dec. at 27. None of the treating physicians who contemporaneously examined Petitioner drew a connection from the cardiac event to the vaccine. Dec. at 7-8, 28-29. Indeed, the Special Master noted that even though Dr. Cordas was aware that Petitioner was pursuing a vaccine-injury claim, he nevertheless could not "directly link" Petitioner's flu vaccination to her October 19, 2011 cardiac arrest, because "'[n]o symptoms

typical of anaphylactic or anaphylactoid reactions [were] related to the vaccine . . .'" Dec. at 11 (citing Pet'r's Ex. 30 at 2 (ECF No. 35-1)).

Petitioner attempts to sidestep this absence of causation evidence by arguing that the treating physicians did not test Petitioner's inflammatory process because these tests are not routinely administered after a cardiac event. Pet'r's Br. at 7 (citing Dec. at 28-29). This argument is unavailing because, as noted, Petitioner did receive medical tests which could have confirmed Petitioner's theory. For instance, Petitioner's prothrombin time was measured shortly after Petitioner's cardiac arrest but was found to be within the normal limits. Dec. at 29 (citing Pet'r's Ex. 24 at 190, 218). As the Special Master stated, this evidence undermines Dr. Stark's prothrombotic theory. *Id*. Additionally, Petitioner's cardiac catheterization report, which was done shortly after her cardiac arrest, did not show "an acute myocardial infarction of a small vessel such as slow coronary flow or vessel that was occluded." Dec. at 20 (quoting Resp't's Ex. H. at 4). The Special Master found, and this Court agrees, that these results weighed against Dr. Stark's proposition of a vaccine-induced prothrombotic state leading to cardiac arrest in Petitioner's case. Dec. at 20, 26.

Moreover, under the arbitrary and capricious standard, if a special master's "conclusion [is] based on evidence in the record that was not wholly implausible, [the Court is] compelled to uphold that finding as not being arbitrary or capricious." *Lampe*, 219 F.3d at 1363. It is not enough for an appellant to point to alternative conclusions the special master could have drawn or to point to inferential steps the special master might have taken. *See id*. Thus, in the absence of any objective evidence to support Petitioner's theory and taking into account her own expert's statement that he could not "directly link the cardiac arrest to the flu shot," *see* Dec. at 11 (citation omitted), this Court cannot find that the Special Master acted arbitrarily in declining to conclude

that the vaccine caused Petitioner's cardiac arrest. *See Moberly ex rel. Moberly*, 592 F.3d at 1323-24 (holding that the special master did not err in rejecting the expert's theory of causation when no treating physician ever drew a causal link between petitioner's injury); *see also Burns by Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that the decision of whether to accord greater weight to contemporaneous medical records or later given testimony is "uniquely within the purview of the special master.") (citations omitted).

For these reasons, the Court concludes that the Special Master did not err or act in an arbitrary or capricious manner in determining that Petitioner failed to satisfy *Althen* prong two.

CONCLUSION

This Court holds that the findings of the Special Master are not arbitrary and capricious. The Special Master properly found that Petitioner failed to show by preponderant evidence that the vaccination at issue brought about her injury under either *Althen* prongs I and II. *Althen*, 418 F.3d at 1278.

Therefore, the Court **DENIES** Petitioner's Motion for Review (ECF No. 106) and **SUSTAINS** the Decision of the Special Master. The parties shall separately file any proposed redaction to this Memorandum and Order, with the text to be redacted clearly blacked out, by December 16, 2020. The Clerk of Court is directed to enter judgment accordingly.

IT IS SO ORDERED.

s/ Eleni M. Roumel
ELENI M. ROUMEL
Chief Judge

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Washington, D.C.